

Package leaflet: Information for the user

Fungasil 250mg Tablets

Terbinafine hydrochloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Fungasil is and what it is used for
2. What you need to know before you take Fungasil
3. How to take Fungasil
4. Possible side effects
5. How to store Fungasil
6. Contents of the pack and other information

1. What Fungasil is and what it is used for

Fungasil contains the active substance terbinafine hydrochloride. Terbinafine belongs to a group of medicines called antifungal agents.

Fungasil is used to:

- treat fungal skin infections caused by parasitic fungus that infects the skin (dermatophytes) such as:
 - Tinea corporis (fungal infection anywhere on the skin except on the head, hands, feet or groin. This especially affects the hairless parts of the skin).
 - Tinea cruris (a fungal infection of the groin)
 - Tinea pedis (commonly called Athlete's Foot – a fungal infection of the feet. This usually affects the skin between the toes)
- treat fungal infections of the nails (onychomycosis) which are caused by parasitic fungus that infects the skin (dermatophytes).

Terbinafine is not effective against Pityriasis versicolor (a skin infection caused by yeasts).

2. What you need to know before you take Fungasil

DO NOT take Fungasil

- if you are allergic to terbinafine hydrochloride or to any of the other ingredients of this medicine (listed in section 6).
- if you suffer from severe kidney disease (when your kidneys are not working properly). Your doctor will tell you if you can take this medicine.
- if you suffer from chronic or acute liver disease (when your liver disease has persisted for a long time or is presently not working properly). Your doctor will tell you if you can take this medicine.

Warnings and precautions

Talk to your doctor or pharmacist before taking Fungasil.

Before starting treatment with Fungasil your doctor should verify any pre-existing liver problems, or determine if you are at present suffering from a liver disease, because in very rare cases terbinafine may trigger liver failure in patients with or without previous liver diseases (see also sections 2. DO

NOT take Fungasil and 4. Possible side effects).

Please tell your doctor immediately if you are suffering or have ever suffered from any of the following conditions or illnesses:

- **liver disease.** Terbinafine can rarely cause:
 - cholestasis (when bile cannot flow properly from the liver) and
 - hepatitis (inflamed liver)

These rare side effects normally occur within the first two months of treatment. Tell your doctor if you notice signs of a liver disease such as:

- pruritus (itching)
- feeling sick without any obvious reason (unexplained persistent nausea)
- loss of appetite (anorexia)
- tiredness
- jaundice (yellowing of the skin or eye-balls)
- vomiting
- abdominal pain (tummy pain)
- dark coloured urine
- pale stools

Your doctor will check your liver function directly. You may have to stop taking terbinafine.

If you have a high fever or a sore throat your doctor will check your blood function. Terbinafine can rarely cause blood disorders.

Tell your doctor or pharmacist if you have or have had any medical conditions, especially any of the following:

- **skin problems** such as rash, red skin, blistering of the lips, eyes or mouth, skin peeling (signs of serious skin reactions).
- **psoriasis (a skin condition).** Very rarely Fungasil may make this worse.
- **poor kidney function.** Your dose of Fungasil may have to be reduced.

If an immune system weakness is presumed your doctor will consider doing a full blood count after 6 weeks of Fungasil use.

Patients with reduced liver function

Fungasil must not be used by patients with chronic or active liver disease.

Other medicines and Fungasil

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Terbinafine affects the way the liver removes certain other medicines from the body. These medicines are listed in this section. Your doctor knows which these medicines are and will adjust the doses as necessary.

You must take special care if you are also taking any of the following medicines:

Medicines that affect terbinafine:

- rifampicin (antibiotic used to treat infections such as tuberculosis). Rifampicin may reduce the effect of terbinafine.
- cimetidine (used to treat certain disease of the stomach or bowel). Cimetidine may increase the effect of terbinafine.
- fluconazole or ketoconazole (medicine used to treat fungal infections)

- amiodarone (medicine used to treat heart problems)

Medicines that are affected by terbinafine:

- certain antidepressants (medicines used to treat depression - feeling sad):
 - tricyclic antidepressants (e.g. amitriptyline, clomipramine, imipramine, desipramine)
 - selective serotonin reuptake inhibitors (SSRIs, e.g. citalopram, escitalopram, fluoxetine)
- beta-blockers (used to treat high blood pressure) (e.g. atenolol, propranolol, bisoprolol)
- monoamine-oxidase type B inhibitors (used to treat Parkinson's disease, e.g. selegiline, rasagiline)
- ciclosporin, a medicine used to control your body's immune system in order to prevent rejection of transplanted organs
- caffeine

The effect of these medicines may be increased. Your doctor will adjust the dose, if necessary.

Oral contraceptives

Some women taking oral contraceptives at the same time as terbinafine have developed:

- breakthrough bleeding (bleeding from the vagina occurring between menstrual periods)
- irregular menstrual cycles (when menstrual bleeding occurs at irregular intervals).

Fungasil with food and drink

Terbinafine can be taken with or without food.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

Terbinafine may harm the unborn child. Therefore, you should not take Fungasil if:

- you are pregnant
- you think you may be pregnant
- you are trying to become pregnant.

If you become pregnant while you are taking Fungasil, you should stop taking the tablets immediately and tell your doctor.

Breast-feeding

You should not breast-feed while taking this medicine because your baby would be exposed to terbinafine through your breast milk. This might harm your baby.

Driving and using machines

Terbinafine is not known to have any considerable effect on your ability to drive or use machines. If you feel dizzy while taking Fungasil tablets, do not drive or use machines.

Fungasil contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Fungasil

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Swallow the medicine with a sufficient amount of water.

Dosage:Adults

The recommended dose is 250 mg once per day.

Patients with poor kidney function

This medicine is not recommended for patients with poor kidney function, therefore talk to your doctor before taking this medicine.

Use in children

If you are a child you should not take Fungasil.

Elderly patients

There are not indications that elderly patients require a different dosage. However, pre-existing liver or kidney function disorder must be taken into account (see also sections 2. What you need to know before you take Fungasil and 4. Possible side effects).

Duration of treatment

This depends on the type of infection you have and how severe it is.

Skin infections

You should take Fungasil for 2–4 weeks to treat:

- Tinea pedis (Athlete's foot)
- Tinea corporis (fungal infection anywhere on the skin except on the head, hands, feet or groin)
- Tinea cruris (a fungal infection of the groin)

In certain types of tinea pedis you may have to take Fungasil for up to 6 weeks. For example:

- interdigital tinea pedis (between the toes)
- plantar/moccasin-type tinea pedis (on the bottom and sides of the foot)

Your doctor will recognise these types and will tell you for how long to continue treatment.

Note that the symptoms of your infection may not disappear completely until several weeks after it has been cured.

Nail infection (onychomycosis)

You should take terbinafine for 6–12 weeks to treat:

- infection affecting the fingernails.

In certain types of nail infection you may have to take Fungasil for longer.

For example:

- infection affecting the toenails

Most infections affecting the toenails require treatment for 12 weeks. However, you may need to take Fungasil for up to 6 months. This depends on how well your nails grow back over the first few weeks of treatment.

Note that the signs and symptoms of your infection may not disappear completely until several weeks after it has been cured. It can take several months for the healthy nails to grow back.

If you take more Fungasil than you should

If you accidentally take too many tablets, contact your doctor or nearest hospital emergency department immediately for advice.

Symptoms of overdose include:

- headache

- nausea (feeling sick)
- stomach pain
- dizziness

If you forget to take Fungasil

If you forget to take a dose of Fungasil, just take the next dose at the usual time. Do not try to make up for the missed dose and do not take two doses at once.

If you stop taking Fungasil

Do not stop or change your treatment before talking to your doctor, even if your symptoms improve.

Your doctor has told you how long you should take Fungasil. You should follow the instruction of your treating doctor to complete your course of treatment. This is important to ensure the best possible therapeutic outcome. If you stop the treatment earlier than agreed, your symptoms may come back.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects although not everybody gets them.

If changes or loss of the sense of taste, severe changes in your blood count or worsening of skin reactions occur during treatment with Fungasil, you must stop taking terbinafine immediately.

Some side effects are serious in nature and occur rarely or very rarely. If you experience any of these side effects, stop taking Fungasil and seek medical attention immediately.

- Symptoms such as unexplained persistent nausea, stomach problems, loss of appetite or unusual tiredness or weakness or if you notice that your skin or the whites of your eyes look yellow, that your urine is unusually dark or your bowel motions are unusually light in colour (possible signs of liver problems).
- Symptoms such as a sore throat with fever and shivering or if you experience unusual bleeding or bruising (possible signs of diseases that affect the level of certain types of blood cells).
- Symptoms such as abnormal pale skin, mucosal lining or nail beds, unusual tiredness or weakness or breathlessness on exertion (possible signs of a disease that affects the level of red blood cells).
- Symptoms of a severe allergic reaction (anaphylaxis/angioedema) such as:
 - swollen face, tongue or throat
 - difficulty swallowing
 - hives and/or difficulty breathing
- Symptoms of serum sickness-like reaction (an allergic reaction) such as:
 - skin rash or urticaria (hives)
 - arthralgia (joint pain) and/or myalgia (muscle pain)
 - swelling of the skin of the face and/or swollen glands
 - dyspnoea (difficulty breathing)
- Severe skin reactions, e.g. Stevens-Johnson syndrome, toxic epidermal necrolysis (skin reactions that cause redness, blistering and peeling of the skin), acute generalised exanthematous pustulosis (formation of numerous pustules mostly combined with fever and joint pain), Erythema exsudativum multiforme (inflammatory skin reaction that may cause circular reddish dots on the skin occasionally becoming bullous), Photosensitivity reaction (an excessive sensitivity of the skin to sunlight, increasing the risk of sunburn)
- Appearance or aggravation of cutaneous or systemic lupus erythematosus. These are diseases of the immune system (which normally protects the body). They affect the skin (skin rash) and can affect certain internal organs, causing:
 - pericarditis (inflammation of the membranes surrounding the heart with chest pain, radiating to the back and relieved by sitting up forward and worsened by lying down)
 - pleuritis (inflammation of the membranes surrounding the lungs which may cause painful

- breathing, shortness of breath and/or cough)
 - arthritis (inflammation of the joints which may cause pain)
 - myalgia (muscle pain)
- Symptoms such as rash, fever, itching, tiredness or if you notice the appearance of purplish-red spots under the skin surface (possible signs of blood vessel inflammation).
- Severe upper stomach pain with radiation to the back (possible signs of pancreas inflammation).
- Unexplained muscle weakness and pain or dark (red-brown) urine (possible signs of muscle necrosis).

Very common side effects (may affect more than 1 in 10 people):

- Decreased appetite
- Bloating stomach (abdominal distension)
- Indigestion (dyspepsia)
- Feeling sick (nausea)
- Stomach pain (abdominal pain)
- Diarrhoea
- Skin rash
- Urticaria (hives)
- Arthralgia (pain in the joints) and/or myalgia (muscle pain). These side effects may occur as part of an allergic reaction. They may be associated with allergic skin reactions

Common side effects (may affect up to 1 in 10 people):

- Loss of appetite
- Headache
- Fatigue (tiredness)
- Malaise (feeling unwell)

Uncommon side effects (may affect up to 1 in 100 people):

- Ageusia (loss of the sense of taste)
- Dysgeusia (abnormal sense of taste)
- Hypogeusia (decrease in taste sensitivity)

Rare side effects (may affect up to 1 in 1,000 people):

- Anaphylactic reaction (a severe allergic reaction), angioedema (swelling of the skin of the face and throat, which may cause difficulty breathing) and serum sickness-like reaction (see also paragraph “some side effects are serious in nature and occur rarely or very rarely” above)
- Dizziness
- Hypoaesthesia (slight numbness of the skin)
- Paraesthesia (feeling of pins and needles)
- Cholestasis (when the bile produced by the liver cannot flow properly. This makes the skin turn yellow), impaired liver function (when the liver does not work properly), hepatitis (inflammation of the liver), jaundice (yellow skin) (see also “2. Warnings and precautions”)
- Liver failure followed by liver transplantation or death. In the majority of these cases, patients were suffering from serious underlying diseases
- Raised liver enzyme levels (a blood test which shows damage to the liver) (see also “2. Warnings and precautions”)

Very rare side effects (may affect up to 1 in 10,000 people):

- Changes in the number of certain blood cells
 - low number of white blood cells (neutropenia or agranulocytosis). This may cause unexplained fever or flu-like symptoms, such as sore throat.

- low number of blood platelets (thrombocytopenia). (These are required for the blood to clot. A low number of blood platelets may cause easy bruising or nose bleeds).
- tell your doctor if you notice increased frequency of infection, fever, sore throat, bruising easily or bleeding.
- Certain skin reactions: cutaneous (in the skin) or systemic (in the circulation) lupus erythematosus (if you have such a disease already it may get worse), photosensitivity (increased sensitivity of the skin to sunlight) and/or severe skin reactions that cause redness, blistering and peeling of the skin called:
 - Stevens-Johnson syndrome
 - Toxic epidermal necrolysis
 (see also paragraph “some side effects are serious in nature and occur rarely or very rarely” above)
- Anxiety
- Depression (feeling sad)
- Psoriasis may get worse (psoriasis is a disease in which the skin becomes scaly. It can also affect the nails and the joints, causing arthritis) (see also “2. Warnings and precautions”)
- Hair loss (alopecia)
- Irregular menstruation (in women, when your menstrual period occurs at irregular intervals) (especially in women who take oral contraceptives)
- Breakthrough bleeding (in women, bleeding from the vagina that occurs between the menstrual periods) (especially in women who take oral contraceptives)

Frequency not known (frequency cannot be estimated from the available data)

- Anaemia
- Smell disorders including permanent loss of smell (anosmia)
- Decreased hearing (hypoacusis), hearing impaired, ringing in the ears (tinnitus)
- Inflammation of blood vessels (vasculitis)
- Inflammation of the pancreas (pancreatitis)
- Muscle necrosis (rhabdomyolysis)
- Flu-like symptoms (e.g. tiredness, chills, sore throat, joint or muscles aching) (influenza like illness), fever (pyrexia)
- Blood creatinine phosphokinase increased, weight decreased (secondary to decrease in taste sensitivity)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Fungasil

Keep this medicine out of the sight and reach of children.

You should store the blister strip in the outer carton.

Do not use this medicine after the expiry date, which is stated on the carton and blister pack after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater <or household waste>. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Fungasil contains

The active substance is terbinafine hydrochloride.

One tablet contains 250 mg of terbinafine (as hydrochloride).

The other ingredients are:

- microcrystalline cellulose
- hypromellose
- sodium starch glycolate
- colloidal anhydrous silica
- magnesium stearate

What Fungasil 250 mg tablets look like and contents of the pack

Fungasil 250 mg tablets are white or almost white, round tablets that are convex on both sides. They have a break line on one side and 250 engraved on the other.

Fungasil is available in PVC/aluminium blister packs.

Fungasil 250 mg tablets are available in packs containing 7, 8, 14, 15, 28, 30, 42, 45 and 98 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and manufacturer

Marketing authorisation holder:

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

Manufacturers:

Gedeon Richter Plc, 1103 Budapest, Gyömroi út 19-21, Hungary

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria:	Terbinafine "Stada" 250 mg Tabletten
Denmark:	Terbinafine Stada
Germany:	Terbinafin STADA 250 mg Tabletten
Ireland:	Fungasil 250 mg Tablets
Italy:	Terbinafine EG
Portugal:	Terbinafina Ciclum 250 mg comprimidos
Sweden:	Terbinafin STADA 250 mg tablett

This leaflet was last revised in September 2020.